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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,545	04/05/2006	Enrico Anthony Antonini	1679 WO/US	4059

7590 07/17/2008  
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EXAMINER
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CHANDRAKUMAR, NIZAL S

ART UNIT	PAPER NUMBER
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1625

MAIL DATE	DELIVERY MODE
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07/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/574,545	<b>Applicant(s)</b> ANTONINI, ENRICO ANTHONY	
	<b>Examiner</b> NIZAL S. CHANDRAKUMAR	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/24/2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

#### DETAILED ACTION

Applicants response filed 05/07/2008 is acknowledged.

Claims 1, 3-25 are pending. Claims 1,3-5, 7,12-14, 24-25 have been amended.

Response to Applicants Remarks:

#### ***Claim Rejections - 35 USC § 112***

Applicants amendments including claims limitations and persuasive arguments overcome the previously presented rejections under 35 USC § 112 first and second paragraphs.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Previously presented rejection of claims 1, 3-25 under 35 U.S.C. 103(a) as being unpatentable over Hofstadter is maintained. Applicants arguments were fully considered and are not found persuasive.

Applicant argues that the instantly claimed process of purification of fentanyl including the claim limitations of (percent impurity phenylethylpiperaniline), the limitations of loading ratio, the employment of collecting fractions/recycling, differ from the teaching of Hofstadter process of purification of linomycin comprising different sets of process conditions. Applicant argues that the office action failed in (1) clear articulation of some TSM of the each and every limitation of the claimed invention; (2) showing reasonable expectation of success (3) lack of secondary consideration in support of Graham factual inquiries. As such, the applicant argues that the office failed to establish prime facie case of obviousness.

Applicant's arguments are not persuasive for reasons of record. The process of purification of organic chemicals by reverse phase high performance chromatography is well known in the art at the

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time of the instant application. Hofstadter is but one example of the reverse phase hplc preparative purification of organic molecules. Applicant admits on page 9, lines 13-14, of the remarks that 'in general, preparative liquid chromatography is a well known and understood separation technique'. Optimization of loading ratio, solvent systems, recycling etc based on the results of analytical hplc data, for the scale-up for preparative is within the skill of one skilled in the art. See for example, WO 03/074526 A2 (cited in IDS of copending application # 11576,059) under 'Background of the Invention'. Examiner agrees that the Hofstadter reference or other references cited (but not used) in the previous office action do not recite the exact limitations of the instant claims. But all the claimed elements such as (determination of) loading ratio etc are known in the prior art and one skilled in the art of purification technology could have combined and modified the elements known in the prior art methods in the optimization of purification of a given sample of impure fentanyl, and the routine optimization of such elements would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Such optimization of routine methods is part of the ordinary capabilities of a person of ordinary skill in the art, in view of teachings such as that of Hofstadter.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIZAL S. CHANDRAKUMAR whose telephone number is (571)272-6202. The examiner can normally be reached on 8.30 AM - 4.30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571 0272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nizal S. Chandrakumar

/D. Margaret Seaman/  
Primary Examiner, Art Unit 1625